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Certifier A. Corbin

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0113]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments." This guidance document describes a means by which root-form endosseous dental implants and endosseous dental implant abutments may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify these devices from class III to class II (special controls).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send

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one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Angela Blackwell, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 14, 2002 (67 FR 34458), FDA announced the availability of a draft of this guidance document and invited interested persons to comment on it by August 12, 2002. FDA received a total of five comments on the proposed guidance and reclassification rule. Four comments sought clarification in the guidance document about the following issues: (1) Table of risks to health and mitigation measures and (2) fatigue testing. FDA revised the table extensively to communicate the risks more clearly and to improve the correlation between risks and mitigations without deleting any risks or mitigations. Although FDA disagreed with the comments about fatigue testing, as stated in the guidance document, the agency will consider other ways that show equivalent assurances of safety and effectiveness. In response to comments, FDA also modified other areas of the guidance document for clarity.

The guidance document provides a means by which root-form endosseous dental implants and endosseous dental implant abutments may comply with the requirement of special controls for class II devices. Following the effective date of the final reclassification rule, any firm submitting a 510(k) for the devices will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Also in the **Federal Register** of May 14, 2002 (67 FR 34416), FDA proposed to reclassify root-form endosseous dental implants and endosseous dental implant abutments into class II with this guidance document as the special control. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify root-form endosseous dental implants and endosseous dental implant abutments from class III (premarket approval) to class II (special controls).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on root-form endosseous dental implants and endosseous dental implant abutments. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if the approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments" by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-

On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1389) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

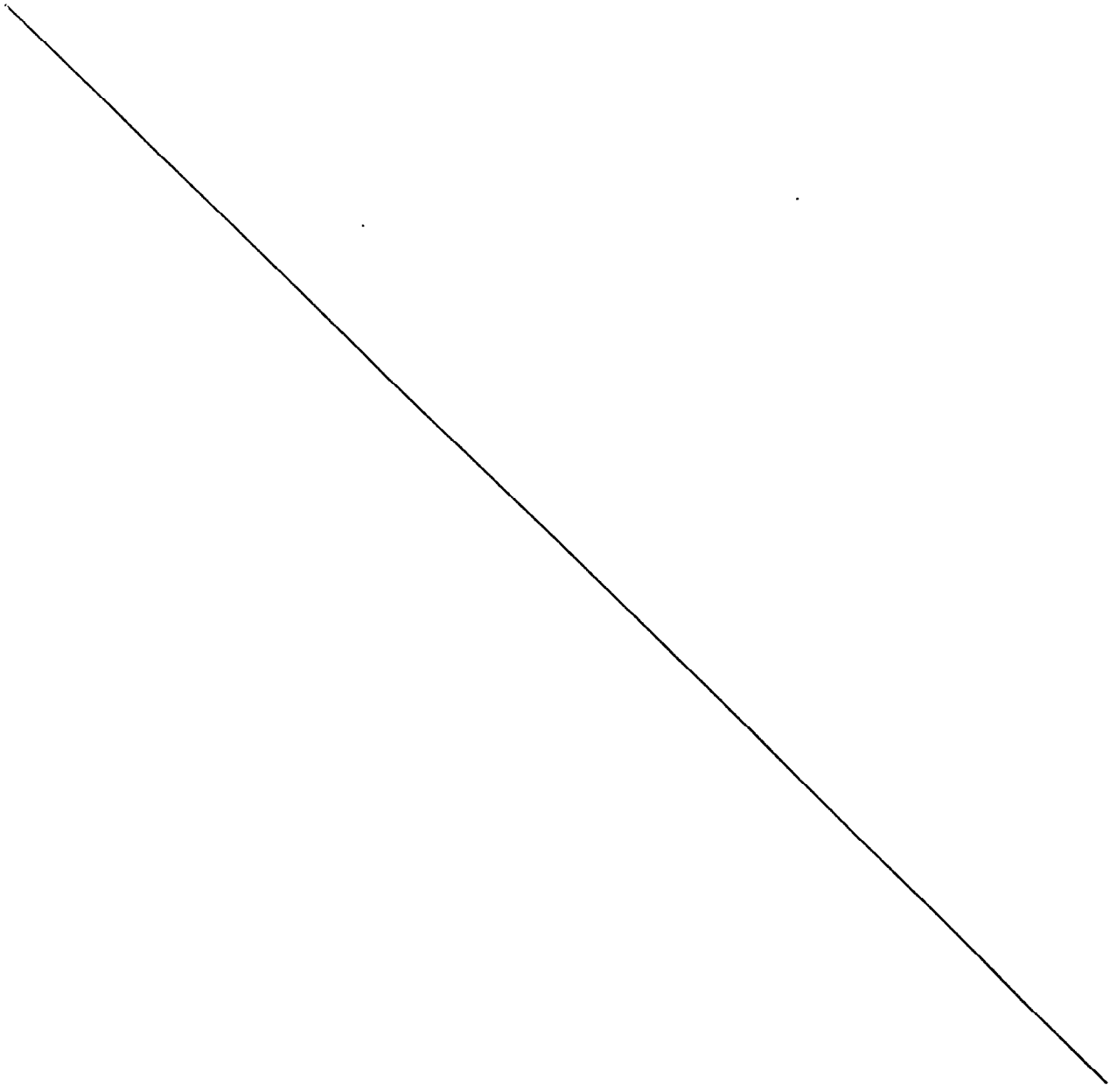
Persons interested in obtaining a copy of the guidance also may do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh.* A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html.* Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets.*

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document at any time. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with



the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/3/04
May 3, 2004.

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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